

EXHIBIT C

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

3 IN RE: ETHICON, : Master File No.
4 INC. PELVIC : 2:12-MD-02347
5 REPAIR SYSTEM : MDL No. 2327
6 PRODUCTS :
7 LIABILITY :
8 LITIGATION :
9 ----- :
10 ROSE GOMEZ, et al : Joseph R. Goodwin
11 Case No. : U.S. District Judge
12 2:12-cv-00344 :
13

14 - - -

15 Thursday, March 31, 2016

16 - - -

17 Oral deposition of JULIE DROLET, M.D.,
18 taken pursuant to notice, at the Courtyard
19 by Marriott York, 2799 Concord Road, York,
20 Pennsylvania, commencing on the above date
21 at or about 10:05 a.m., before Eileen P.
22 Barth, C.S.R., N.P.

23 - - -

24 GOLKOW TECHNOLOGIES, INC.

25 877.370.3377 ph | 917.591.5672 fax
26 deps@golkow.com

| Page 2 | Page 4 |
|--|--|
| <p>1 APPEARANCES: 2 ZONIES LAW LLC 3 BY: JOSEPH ZONIES, ESQUIRE 4 GREG BENTLEY, ESQUIRE 5 1900 Wazee Street 6 Suite 203 7 Denver, CO 80202 8 Jzonies@zonieslaw.com 9 Gbentley@zonieslaw.com 10 Attorneys for the Plaintiff</p> <p>11 DRINKER BIDDLE & REATH, LLP 12 BY: MELISSA A. GRAFF, ESQUIRE 13 One Logan Square 14 Suite 2000 15 Philadelphia, PA 19103-6996 16 Melissa.Graff@dbr.com 17 Attorneys for the Defendants</p> | <p>1 INDEX 2 3 WITNESS PAGE 4 JULIE DROLET, M.D. 5 By Mr. Zonies 5 6 7 8 EXHIBITS 9 EXHIBIT DESCRIPTION PAGE 10 Exhibit 1 Binder 1 of 1 48 11 Exhibit 2 Binder 2 of 2 48 12 Exhibit 3* Thumb Drive 48 13 Exhibit 1-A Drolet Case Specific 58 14 Gomez Report 15 Exhibit 4 Julie Drolet Reliance 62 16 List in Addition to 17 Material Reference in 18 Report, Rose Gomez 19 20 (*Thumb Drive Retained by Mr. Bentley) 21 22 23 24</p> |
| Page 3 | Page 5 |
| <p>1 DEPOSITION SUPPORT INDEX 2 3 DIRECTIONS NOT TO ANSWER 4 PAGES: None 5 REQUESTS FOR DOCUMENTS OR INFORMATION 6 PAGES: None 7 8 STIPULATIONS AND/OR STATEMENTS: 9 PAGES: None 10 MARKED QUESTIONS: 11 PAGES: None 12 13 14 15 16 17 18 19 20 21 22 23 24</p> | <p>1 JULIE DROLET, M.D., having 2 been duly sworn, was examined and 3 testified as follows: 4 BY MR. ZONIES: 5 Q. Good morning, Doctor. Would 6 you please state your full name for the 7 record? 8 A. Julie Drolet. 9 Q. And how do you spell your 10 last name? 11 A. D as in doctor, R as in Rio, 12 O as in omega, L as in lima, E, T as in 13 Texas. 14 Q. Doctor, you understand that 15 you're here today as an expert witness in 16 the Ethicon transvaginal mesh litigation; 17 correct? 18 A. That is correct. 19 Q. What's your understanding of 20 what your role is today as an expert 21 witness? 22 A. To give deposition today 23 about Prolift+M and TVT-O. 24 Q. And we're going to start the</p> |

| Page 6 | Page 8 |
|---|---|
| <p>1 morning with the Prolift+M device. Is 2 that okay?</p> <p>3 A. Sure.</p> <p>4 Q. Doctor, have you given a 5 deposition before?</p> <p>6 A. Yes, I have.</p> <p>7 Q. How many times?</p> <p>8 A. Total? Three.</p> <p>9 Q. And you gave a deposition in 10 a case entitled Hammons; is that right?</p> <p>11 A. Yes. That would have been 12 my first deposition for an expert.</p> <p>13 Q. And that's H-A-M-M-O-N-S?</p> <p>14 A. As best I can recall.</p> <p>15 Q. I don't want to go over the 16 territory in the Hammons deposition again 17 if I can help it, so I'll try to preface 18 most of my questions with since the 19 Hammon deposition or Hammons and ask you 20 the questions. Is that okay? Do you 21 understand what I mean by that?</p> <p>22 A. I do.</p> <p>23 Q. So for example since the 24 Hammons deposition, have you given any</p> | <p>1 A. As a resident probably in 2 the late '80s.</p> <p>3 Q. And when did you first use a 4 kit? Do you know what I mean when I say 5 a kit?</p> <p>6 A. Commercially available 7 device, mesh, and application device?</p> <p>8 Q. Correct.</p> <p>9 A. Yes. Did that probably 10 sometime in May 2005.</p> <p>11 Q. And what was the first mesh 12 kit that you used?</p> <p>13 A. For pelvic organ prolapse?</p> <p>14 Q. Yes.</p> <p>15 A. Prolift.</p> <p>16 Q. Have you used -- well, when 17 do you think the last time was that you 18 used a pelvic organ prolapse mesh kit?</p> <p>19 A. That included the 20 application devices? Probably 2010, 21 2011.</p> <p>22 Q. And then since that time in 23 2010 or 2011 you've continued to use 24 synthetic meshes for treatment of</p> |
| <p>1 other depositions?</p> <p>2 A. No, I have not.</p> <p>3 Q. And do you have a 4 recollection of when the Hammons 5 deposition was?</p> <p>6 A. Friday, November 13th, 2015.</p> <p>7 Q. You have a recollection.</p> <p>8 That's for sure. Good.</p> <p>9 Did you ultimately testify 10 in trial at the Hammons case?</p> <p>11 A. I did not.</p> <p>12 Q. Do you know why not?</p> <p>13 MS. GRAFF: Objection.</p> <p>14 THE WITNESS: I do not.</p> <p>15 BY MR. ZONIES:</p> <p>16 Q. Do you understand that it 17 did go to trial?</p> <p>18 A. I do.</p> <p>19 Q. And what do you understand 20 the outcome of that case to be?</p> <p>21 A. I think the verdict went to 22 the plaintiff.</p> <p>23 Q. Doctor, when did you begin 24 using synthetic meshes to treat prolapse?</p> | <p>1 prolapse?</p> <p>2 A. I have.</p> <p>3 Q. And are you -- what type 4 of -- what are you using in that 5 application if not a kit?</p> <p>6 A. At this time I'm using 7 Restorelle vaginal mesh. For 8 sacrocolpopexies I have done various Y 9 meshes, Y-shaped meshes from different 10 companies.</p> <p>11 Q. Can you name the companies' 12 meshes?</p> <p>13 A. I've used different 14 configuration of the Bard mesh, the 15 Restorelle mesh, we're looking at now 16 Boston Scientific, I've used Gynemesh in 17 different configurations as well.</p> <p>18 Q. When you switched from using 19 commercially-available kits to using 20 Restorelle, you testified that that was 21 in about 2010, 2011? Is that right?</p> <p>22 A. That would be about right.</p> <p>23 Q. When you made that switch, 24 did you -- since the switch, have you had</p> |

| Page 10 | Page 12 |
|--|--|
| <p>1 success in your operations?</p> <p>2 A. I have.</p> <p>3 Q. Have you had success that's</p> <p>4 been about equal to what you feel you had</p> <p>5 with the commercially-available mesh</p> <p>6 kits?</p> <p>7 A. It depends on your</p> <p>8 definition of success.</p> <p>9 Q. Cure of the prolapse.</p> <p>10 A. In the treated compartment?</p> <p>11 Q. Yes.</p> <p>12 A. I don't have the exact</p> <p>13 figures, but I would say about the same</p> <p>14 or a little less.</p> <p>15 Q. A little less success?</p> <p>16 A. Now, yes. I've had mesh</p> <p>17 disinserted from the sacrospinous</p> <p>18 ligaments.</p> <p>19 Q. Can you explain what you</p> <p>20 mean by that?</p> <p>21 A. That there was a good</p> <p>22 suspension for a few weeks, months, and</p> <p>23 suddenly without a recurrence of the true</p> <p>24 cystocele and/or rectocele the apex fell</p> | <p>1 using the commercial kits?</p> <p>2 MS. GRAFF: Object to form.</p> <p>3 THE WITNESS: I don't know</p> <p>4 if I could call it happy to stop</p> <p>5 the commercial kits, no. It was a</p> <p>6 question of what else is there out</p> <p>7 there, hospital purchasing</p> <p>8 decisions, combined.</p> <p>9 BY MR. ZONIES:</p> <p>10 Q. Did you voice any</p> <p>11 disagreement with the hospital about</p> <p>12 their purchasing decisions to stop</p> <p>13 purchasing commercially-available kits</p> <p>14 such as the Prolift?</p> <p>15 A. I don't recall.</p> <p>16 Q. How would you describe your</p> <p>17 success with after -- strike that.</p> <p>18 How would you describe your</p> <p>19 post-commercial kit success rates in the</p> <p>20 non-treated compartments?</p> <p>21 A. As good as with the kits.</p> <p>22 Q. How would you describe the</p> <p>23 complications and adverse events that</p> <p>24 your patients experienced --</p> |
| <p>1 in my vaginal meshes, and that is only</p> <p>2 for vaginal mesh. Not sacrocolpopexies.</p> <p>3 Those successes has been the same</p> <p>4 throughout the years.</p> <p>5 Q. Why did you choose to stop</p> <p>6 using commercially-available mesh kits?</p> <p>7 MS. GRAFF: Object to form.</p> <p>8 You can answer.</p> <p>9 THE WITNESS: After the FDA</p> <p>10 of 2008 and closer to 2010, 2011</p> <p>11 where literature was coming out</p> <p>12 about different kinds of mesh that</p> <p>13 were now available without kits,</p> <p>14 the hospital had already a</p> <p>15 contract with Coloplast which</p> <p>16 bought Restorelle and it was kind</p> <p>17 of a joint decision for me to try</p> <p>18 this and that's how it happened;</p> <p>19 and eventually Gynecare stopped</p> <p>20 producing their kits, so it was a</p> <p>21 no brainer around that time.</p> <p>22 BY MR. ZONIES:</p> <p>23 Q. But originally the decision,</p> <p>24 were you happy with your decision to stop</p> | <p>1 MS. GRAFF: Object to form.</p> <p>2 BY MR. ZONIES:</p> <p>3 Q. -- between the commercial</p> <p>4 kits and your time after your last use of</p> <p>5 a commercial kit?</p> <p>6 A. It depends on the kit you're</p> <p>7 talking about. Are we talking about just</p> <p>8 Prolift+M? Are we talking about --</p> <p>9 Q. Let's begin with the</p> <p>10 Prolift+M and then we can expand if you</p> <p>11 think that that would be helpful.</p> <p>12 A. I don't think I can put a</p> <p>13 special number on it, but about the same.</p> <p>14 Q. Do you keep a log of the</p> <p>15 surgeries you've performed and the</p> <p>16 devices you've used in those surgeries?</p> <p>17 A. I don't keep a log of the</p> <p>18 exact devices, but we do have a log of</p> <p>19 all of the patients that went to surgery</p> <p>20 since 2005.</p> <p>21 Q. You started to keep that log</p> <p>22 in 2005?</p> <p>23 A. At least that's the last we</p> <p>24 can find.</p> |

| Page 14 | Page 16 |
|--|---|
| <p>1 Q. You've specifically looked 2 for that? 3 A. Yes, I have. 4 Q. When did you look for that? 5 A. Probably in October of 2015. 6 Q. When you were preparing for 7 your Hammons deposition? 8 A. That would be correct. 9 Q. And can you explain to me 10 what it was that you ultimately found? 11 What does the information and data look 12 like? 13 A. I had my surgery scheduler 14 go through all of the surgical logs for 15 every case I operated since 2005 and go 16 through the dates and just tabulate how 17 many vaginal mesh prolapse surgery I had 18 done and how many slings, midurethral 19 slings. 20 Q. And was that compiled into a 21 spreadsheet of sorts? 22 A. No spreadsheet. Just kind 23 of numbers. 24 Q. And how was that provided to</p> | <p>1 available do you think? 2 A. No, it wouldn't be in the 3 surgery book. I have some recollection 4 of what product I have used, but not 5 precise numbers. 6 Q. So I'd just like to get a 7 sense of what products you used from 2005 8 through 2010-2011 timeframe when you 9 stopped using commercially-available 10 kits. Do you understand that? 11 A. Yes. 12 Q. So starting in 2005, I think 13 you testified that Prolift was the first 14 commercially-available kit that you used; 15 is that right? 16 A. That would be correct. 17 Q. And you were trained on that 18 Prolift by whom? 19 A. By Doctor Vince Lucente. 20 Q. When you created that 21 tabulation of how many surgeries you had 22 performed between 2005 and 2015, did you 23 have that information roughly by year? 24 A. No, I did not. I knew that</p> |
| <p>1 you? 2 A. On a piece of paper. 3 Q. Do you still have that piece 4 of paper? 5 A. Don't think so. 6 Handwritten. 7 Q. And did you update that at 8 all since the Hammons deposition? 9 A. I have not. 10 Q. Do you recollect what the 11 numbers were from 2005 forward for you 12 for the number of prolapse surgeries 13 using vaginal mesh? 14 A. 160 patients received 15 transvaginal mesh for prolapse and 350 16 something for midurethral sling from 2005 17 until 2015 at that time. 18 Q. And when you had that 19 tabulated, did you ask or see information 20 about which types of vaginal mesh 21 prolapse kits you had used over that 22 timeframe? 23 A. I did not. 24 Q. Is that information</p> | <p>1 after 2011 the number of surgeries using 2 vaginal mesh, transvaginal mesh had 3 decreased significantly. 4 Q. So if we start in say May of 5 2005 when you first started to use the 6 Prolift, what was the next commercially 7 available prolapse kit that you used? 8 A. Prolift+M. 9 Q. And when did you start to 10 use Prolift+M? 11 A. I don't recall. I don't 12 remember when the switch was. 13 Q. When you started to use 14 Prolift+M, did you stop using Prolift? 15 A. Yes. 16 Q. So if we assume in 2005 -- 17 or I don't want to assume anything, so 18 let me start over. 19 Starting in 2005 you began 20 using the Prolift kit; correct? 21 A. That is correct. 22 Q. And then subsequently the 23 next kit that you used was the Prolift+M; 24 correct?</p> |

| Page 18 | Page 20 |
|---|---|
| <p>1 A. That would be correct.</p> <p>2 Q. After the Prolift+M, have</p> <p>3 you -- did you use any other</p> <p>4 commercially-available kits for treatment</p> <p>5 of prolapse?</p> <p>6 A. For vaginal prolapse? Yes.</p> <p>7 I can't recall the exact company. I</p> <p>8 think it was either a Bard product, it</p> <p>9 had porcine collagen on it and I used two</p> <p>10 of those and did not use those again, and</p> <p>11 then I think I went -- I might have used</p> <p>12 an Elevate, I'm not quite sure, and then</p> <p>13 went to the Restorelle mesh.</p> <p>14 Q. So you began using</p> <p>15 commercially-available prolapse kits in</p> <p>16 2005 with the Prolift, subsequently you</p> <p>17 stopped using the Prolift and started to</p> <p>18 use exclusively Prolift+M?</p> <p>19 A. That would be correct to the</p> <p>20 best of my recollection.</p> <p>21 Q. And then at some point you</p> <p>22 tried the Bard, what you recollect as the</p> <p>23 Bard Avaulta, but a kit that used a</p> <p>24 porcine collagen in the mesh; is that</p> | <p>1 Q. And do you know of that 150</p> <p>2 how many roughly would have been Prolift</p> <p>3 as compared to Prolift+M?</p> <p>4 A. I do not.</p> <p>5 Q. Do you have a sense of in --</p> <p>6 I know there was sort of a break period</p> <p>7 in your career where you stopped doing</p> <p>8 obstetrics; is that right?</p> <p>9 A. That would be correct.</p> <p>10 Q. In roughly 2008?</p> <p>11 A. November 21st, 2008.</p> <p>12 Q. You're very good with dates.</p> <p>13 A. Certain ones.</p> <p>14 Q. So from May of 2005 through</p> <p>15 that November of 2008, so essentially</p> <p>16 through all of 2008, do you have a sense</p> <p>17 of how many of the 150, 160 kits would</p> <p>18 have been -- you would have used in that</p> <p>19 timeframe? So roughly three and a half</p> <p>20 years?</p> <p>21 A. Yeah, I don't think it has</p> <p>22 anything to do with me stopping</p> <p>23 obstetrics or not. It has to do with the</p> <p>24 overall I think worldwide decline of</p> |
| <p>1 correct?</p> <p>2 A. That would be correct. It</p> <p>3 was coated.</p> <p>4 Q. And you only used two of</p> <p>5 those and then stopped?</p> <p>6 A. Yes.</p> <p>7 Q. And then you moved on to</p> <p>8 perhaps the Elevate?</p> <p>9 A. I'm not sure if I moved on</p> <p>10 or I went back to Prolift+M and then</p> <p>11 eventually moved to the Restorelle, but</p> <p>12 Prolift and Prolift+M have -- I've</p> <p>13 probably done about 150 or something like</p> <p>14 that of the Prolift series using Ethicon</p> <p>15 products.</p> <p>16 Q. So of the 160 total that you</p> <p>17 had your assistant count up, your belief</p> <p>18 is that about 150 of those were either</p> <p>19 Prolift or Prolift+M?</p> <p>20 A. That's to the best of my</p> <p>21 recollection, yes.</p> <p>22 Q. So the vast majority of your</p> <p>23 kits?</p> <p>24 A. That would be correct.</p> | <p>1 pelvic floor mesh utilization, patients</p> <p>2 coming in and saying I don't want that</p> <p>3 mesh on TV or things like that. So I</p> <p>4 don't think the numbers really have been</p> <p>5 affected by me stopping obstetrics. I</p> <p>6 think it's kind of coincidental and other</p> <p>7 external factors. So, it was probably</p> <p>8 consistent throughout and then had I</p> <p>9 stopped obstetrics in 2006 or 2014, the</p> <p>10 rate at which I used the mesh would</p> <p>11 probably have remained the same.</p> <p>12 Q. I understand. So I was just</p> <p>13 trying to give you a point in time where</p> <p>14 it may have made an impact.</p> <p>15 A. No.</p> <p>16 Q. It doesn't?</p> <p>17 A. I don't think it would have.</p> <p>18 Q. I want to try to get the</p> <p>19 scope of the timeframe when you were</p> <p>20 using commercial kits for prolapse. It</p> <p>21 would be roughly May of 2005 through</p> <p>22 somewhere around the end of 2010? Is</p> <p>23 that fair?</p> <p>24 A. 2010, 2011. I can't recall</p> |

| | |
|---|---|
| <p>1 exactly.</p> <p>2 Q. So that would be roughly</p> <p>3 five and a half to six years that you</p> <p>4 were using commercial prolapse kits. Is</p> <p>5 that fair?</p> <p>6 A. Yes, that calculation would</p> <p>7 be fair.</p> <p>8 Q. And it's your belief that of</p> <p>9 the 150 Prolift or Prolift+M kits that</p> <p>10 you used, those would roughly have been</p> <p>11 used by you at a fairly continuous rate</p> <p>12 over that period of time?</p> <p>13 Let me re-ask that. That</p> <p>14 was terrible.</p> <p>15 If we make the assumption</p> <p>16 that it was about a five-year period,</p> <p>17 five-and-a-half-year period that you used</p> <p>18 the commercially-available prolapse kits</p> <p>19 and you did approximately 160 over that</p> <p>20 period of time, it seems like that math</p> <p>21 tells us that you did roughly 30 to 40</p> <p>22 kits per year. Is that fair?</p> <p>23 A. That would be a calculation,</p> <p>24 but I don't know in real numbers if that</p> | <p>Page 22</p> <p>1 A. No.</p> <p>2 Q. We'll talk about that this</p> <p>3 afternoon.</p> <p>4 MS. GRAFF: Objection.</p> <p>5 BY MR. ZONIES:</p> <p>6 Q. Why did you initially try</p> <p>7 the Bard Avaulta?</p> <p>8 A. As reports came out in the</p> <p>9 literature and we looked at more and more</p> <p>10 experiences, there were concerns with</p> <p>11 vaginal mesh erosion, and I'm not sure</p> <p>12 again, you call it Avaulta, I'm not sure</p> <p>13 if that's that company, so whatever mesh</p> <p>14 that I used that had a collagen overlay</p> <p>15 was promoted to me as possibly more</p> <p>16 biocompatible, something like that, and</p> <p>17 so I agreed to try it instead of what I</p> <p>18 was using in a standard fashion and those</p> <p>19 two patients had those dehiscence, and</p> <p>20 although there weren't any long-term</p> <p>21 sequela, I decided that I would not use</p> <p>22 those in my practice. That was my</p> <p>23 experience.</p> <p>24 Q. And that was prior to using</p> |
| <p>1 happened. I have a solo practice and so</p> <p>2 there may be some years where I did it a</p> <p>3 little bit more and then obviously years</p> <p>4 I did a little bit less.</p> <p>5 Q. But there isn't a particular</p> <p>6 year where you did 75 kits in one year</p> <p>7 and another year where you only did 25</p> <p>8 for example?</p> <p>9 A. I don't recall. I don't</p> <p>10 have those numbers for you.</p> <p>11 Q. Why did you only use two of</p> <p>12 the Bard Avaultas?</p> <p>13 A. Because both patients</p> <p>14 presented to me two weeks later with a</p> <p>15 complete dehiscence of their anterior</p> <p>16 incision and I had used the exact same</p> <p>17 sutures, the exact same methods to close</p> <p>18 my vaginal vault. So I brought those</p> <p>19 patients back, re-closed the vaginal</p> <p>20 wall, they did fine, but I never wanted</p> <p>21 to use that product again.</p> <p>22 Q. That's actually something</p> <p>23 you experienced with slings as well,</p> <p>24 correct, with the TVT Secur?</p> | <p>Page 23</p> <p>1 whatever that device was -- well, let me</p> <p>2 ask this. How did you find out about</p> <p>3 that device?</p> <p>4 A. I think a sales rep came to</p> <p>5 my office.</p> <p>6 Q. And that was a fairly normal</p> <p>7 way for you to find out information about</p> <p>8 commercially-available prolapse kits. Is</p> <p>9 that fair to say?</p> <p>10 MS. GRAFF: Object to form.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: No, not</p> <p>13 really. I get a lot of my</p> <p>14 information from the literature</p> <p>15 that I review and obviously those</p> <p>16 companies are named in those</p> <p>17 studies. So I obviously knew of</p> <p>18 different -- the existence of</p> <p>19 different meshes out there and</p> <p>20 different mesh companies. So</p> <p>21 that's not how I get my</p> <p>22 information. I don't get all my</p> <p>23 information from sales reps as you</p> <p>24 suggested.</p> |

| | |
|---|--|
| <p style="text-align: right;">Page 26</p> <p>1 BY MR. ZONIES:</p> <p>2 Q. Right, and I don't mean to 3 suggest that you got all of the 4 information that way, but certainly in 5 your practice you interacted with sales 6 reps from various medical device 7 companies; correct?</p> <p>8 A. From time to time.</p> <p>9 Q. And in this case that we're 10 talking about, this mesh that has a 11 collagen component, you testified that 12 you learned about this mesh through a 13 sales rep that came to your office; is 14 that correct?</p> <p>15 A. That's as best as I can 16 recall.</p> <p>17 Q. And when you performed those 18 two surgeries, was it a sales rep in the 19 room with you?</p> <p>20 A. I can't recall.</p> <p>21 Q. Would you sometimes perform 22 surgeries with the company representative 23 in the room with you?</p> <p>24 A. Yes, it happened. Still</p> | <p style="text-align: right;">Page 28</p> <p>1 parameters so then I can continue 2 implanting a functional lead and not a 3 defective one. So that would be the role 4 of that particular rep.</p> <p>5 The DaVinci robot rep is 6 sometimes in the room as I'm performing 7 surgery. Sometimes I don't know that 8 she's there or not or she came and went. 9 So they come and go and they don't have 10 an active part to play in the surgery. 11 The rep that has the active part would be 12 the rep from the InterStim company.</p> <p>13 Q. And what about when you were 14 doing Prolift and Prolift+M? Ethicon had 15 a sales rep that would attend your 16 surgeries; correct?</p> <p>17 A. Some of the times. Probably 18 in the beginning, yes.</p> <p>19 Q. Do you recall the name I 20 think it's Dave Purcell?</p> <p>21 A. Yes.</p> <p>22 Q. Would Mr. Purcell sometimes 23 attend your surgeries?</p> <p>24 A. Yes, he would.</p> |
| <p style="text-align: right;">Page 27</p> <p>1 happens today.</p> <p>2 Q. And by that what you mean is 3 you'll perform a surgery and a company's 4 sales representative will be in the 5 operating room with you and the patient; 6 correct?</p> <p>7 MS. GRAFF: Object to form.</p> <p>8 THE WITNESS: The sales 9 representative would be in the 10 room, yes.</p> <p>11 BY MR. ZONIES:</p> <p>12 Q. And what is the role of the 13 sales representative when you're doing 14 such a surgery?</p> <p>15 A. It depends.</p> <p>16 Q. What do you mean?</p> <p>17 A. Well, right now the rep that 18 comes in from Medtronic, when I do 19 InterStim neuromodulator implants, the 20 rep has a role as I'm steriley gowned, 21 gloved, and we need to test the leads, I 22 pass an extender cord to the sales rep to 23 make sure that those leads and all the 24 electrodes on the leads are within normal</p> | <p style="text-align: right;">Page 29</p> <p>1 Q. And when he attended a 2 surgery, would he actually scrub in and 3 be gowned as well?</p> <p>4 A. Absolutely not.</p> <p>5 Q. Not?</p> <p>6 A. Not.</p> <p>7 Q. What was his role during 8 those surgeries?</p> <p>9 A. I think at the beginning he 10 would instruct the nurses how to put the 11 cannula through the guide properly. The 12 steps where I needed the mesh, he was 13 able to see where I was in the surgery 14 and assist the nurses and that's it.</p> <p>15 Q. And one of the ways that you 16 described that he would assist the nurses 17 would be to help them I think you said 18 position the cannula? Is that right?</p> <p>19 A. No. When the kit comes, 20 there are the guides which have the 21 handle and the curved metal portion of 22 the guide and then the cannulas, what I 23 call the soft plastic trocars are 24 separate and they need to be threaded or</p> |

| | |
|--|---|
| <p style="text-align: right;">Page 30</p> <p>1 inserted passing through the cannula. 2 But they're not showing them how to 3 insert the cannula. I insert the cannula 4 in the patient.</p> <p>5 Q. Understood.</p> <p>6 A. And the guide.</p> <p>7 Q. So can you describe for me 8 what Mr. Purcell would -- how Mr. Purcell 9 would help your nurses?</p> <p>10 A. Well, he was behind my back 11 because the table and the nurses were 12 behind, but I can hear him, you know, 13 open up the package or give the package 14 to the nurse, the box to the nurse so 15 that the nurse could open the box and 16 then peel the package making sure that 17 they would lift both the mesh and the kit 18 which is still in plastic in a safe 19 sterile manner.</p> <p>20 So he directed what was 21 going on on the table. And if this was a 22 nurse that had never seen Prolift in the 23 first few months or cases that I had 24 done, then he would instruct the nurse</p> | <p style="text-align: right;">Page 32</p> <p>1 Q. And that's in part because 2 you don't, as you said, you don't have a 3 log of specific patients, the specific 4 device you used in that patient and the 5 specific outcome of whether it be safety 6 or efficacy for that patient with that 7 device. Is that fair?</p> <p>8 MS. GRAFF: Object to form.</p> <p>9 THE WITNESS: It would be 10 fair to say that I don't have a 11 specific log for each individual 12 patient. That would be correct.</p> <p>13 BY MR. ZONIES:</p> <p>14 Q. You've never undertaken an 15 analysis of how many patients and which 16 patients you've implanted a certain 17 device on and what the success and safety 18 outcomes were for each of those patients; 19 is that correct?</p> <p>20 A. I've not performed a 21 prospective or retrospective cohort 22 study, but I do see all of my patients 23 postop at two weeks, six weeks, six 24 months and a year, and so it's been my</p> |
| <p style="text-align: right;">Page 31</p> <p>1 how to correctly thread the soft cannula 2 over the guide.</p> <p>3 Q. And aside from that, as the 4 operation went further into it, did he 5 have any role in that room?</p> <p>6 A. Not that I can recall or I'm 7 aware of, no.</p> <p>8 Q. Why did you make the switch 9 from Prolift to Prolift+M?</p> <p>10 A. I don't recall.</p> <p>11 Q. Do you recall how you found 12 out about the Prolift+M?</p> <p>13 A. I don't have a specific 14 recollection, no.</p> <p>15 Q. Did you receive any training 16 specific to the Prolift+M?</p> <p>17 A. No, I did not.</p> <p>18 Q. How would you compare your 19 results from your memory between the use 20 of Prolift and Prolift+M?</p> <p>21 A. I don't think I can track 22 specific results and specific patients. 23 Certainly no worse. Maybe better. I 24 don't know.</p> | <p style="text-align: right;">Page 33</p> <p>1 experience with my patients and reviewing 2 the literature that things are going 3 pretty well.</p> <p>4 Q. And when you say that you 5 have the follow-up with your patients up 6 to one year, that's for patients who 7 continue to see you; is that correct?</p> <p>8 A. Most of them still do.</p> <p>9 Q. But you have some, if this 10 were a study, you would have loss to 11 follow-up for example?</p> <p>12 A. I would expect that.</p> <p>13 Q. I may have asked this and 14 I'm sorry if I did, but did you receive 15 any specific training on the +M?</p> <p>16 A. No, I did not.</p> <p>17 Q. Did you watch any training 18 videos that were specific to the +M prior 19 to using it or while using it in your 20 practice?</p> <p>21 A. Not that I can recall.</p> <p>22 Q. Did you receive any 23 Prolift+M specific instructions for use 24 or IFUs?</p> |

| | |
|--|---|
| <p style="text-align: right;">Page 34</p> <p>1 A. Well, the IFU came with the 2 Prolift+M and all the training and 3 insertion of the mesh was given to me 4 when I went for the Prolift, and so the 5 only thing that changed in the actual kit 6 was the type of mesh, but the cannulas, 7 the retrieval device and the guide were 8 all the same.</p> <p>9 Q. Did you find that the meshes 10 themselves between the Prolift and the 11 Prolift+M were in any way different?</p> <p>12 A. When they come out of the 13 box, I did not notice a huge difference 14 and that's probably because of the 15 Monocryl filament, but the overall weight 16 of the mesh is a little less with 17 Prolift+M than Prolift.</p> <p>18 Q. Out of the box?</p> <p>19 A. So out of the box don't feel 20 much difference, but after the patient 21 has had the Monocryl portion of the mesh 22 resorbed, then the overall amount of 23 polypropylene is less with Prolift+M than 24 with Prolift. So I don't know how it</p> | <p style="text-align: right;">Page 36</p> <p>1 Q. How about at the six-month 2 mark? Did you notice a difference in 3 your examination of the patient between 4 those patients for whom you used Prolift 5 and then as compared to those where you 6 used Prolift+M?</p> <p>7 A. Not anything that was 8 significant that I can recall.</p> <p>9 Q. Have you ever seen a -- 10 strike that.</p> <p>11 Have you ever received any 12 training -- strike that too.</p> <p>13 Have you ever seen any 14 Prolift+M specific videos?</p> <p>15 MS. GRAFF: At any time?</p> <p>16 BY MR. ZONIES:</p> <p>17 Q. At any time.</p> <p>18 A. As I sit here, I'm not sure 19 if it was a specific video for Prolift or 20 Prolift+M.</p> <p>21 Q. So as you sit here, you're 22 not certain whether you've ever seen a 23 Prolift+M specific training video 24 produced by Ethicon for example?</p> |
| <p style="text-align: right;">Page 35</p> <p>1 would feel if I were to, you know, touch 2 a Prolift minus M out of the box.</p> <p>3 Q. When you were using the 4 Prolift+M as compared to the Prolift, did 5 you find that it was easier to work with 6 when you were implanting it than with the 7 Prolift?</p> <p>8 A. I don't recall a specific 9 difference.</p> <p>10 Q. And do you know how long it 11 takes for the resorption to occur?</p> <p>12 A. I think most resorption is 13 done, completed, around 84 days, 90 days.</p> <p>14 Q. And when you would follow-up 15 with a Prolift+M patient of yours, would 16 you notice a difference in your exam of 17 that patient at 90 days as compared to 18 the Prolift?</p> <p>19 A. I wouldn't because I saw 20 patients at two weeks, six weeks, 21 hopefully six months and hopefully a 22 year, so I did not make a specific 23 appointment for them to see me at the 24 three-month mark.</p> | <p style="text-align: right;">Page 37</p> <p>1 A. Not at the time. I think 2 recently I've watched so many videos that 3 were provided for me for this particular 4 case that that might have been part of 5 it, but I don't have the serial number 6 that goes with it off the top of my head.</p> <p>7 Q. In your preparation for 8 today's deposition or the Hammons 9 deposition, did you review some training 10 videos produced by Ethicon?</p> <p>11 A. I reviewed training videos 12 produced by Ethicon, yes.</p> <p>13 Q. Do you have a recollection 14 of whether any of those were specifically 15 Prolift+M training videos?</p> <p>16 A. With the Hammons case it 17 wouldn't have been. It was a Prolift 18 case. And for this case, I can't 19 specifically recall if what I watched was 20 a Prolift or Prolift+M.</p> <p>21 Q. I'd like to talk about what 22 you've done and the work you've done 23 since the Hammons deposition and between 24 today. Okay? So just focusing on your</p> |

| | |
|---|---|
| <p style="text-align: right;">Page 38</p> <p>1 work as an expert witness between 2 November of 2015 and today. Is that -- 3 A. That's correct. Okay. 4 Q. Okay? So subsequent to your 5 deposition in the Hammons case, have you 6 produced any expert reports other than 7 your expert report in this case? 8 A. I have not. 9 Q. Can you tell me what you did 10 to prepare for today's deposition? 11 A. I met with Attorney Graff 12 yesterday, I read my expert report. 13 Q. Anything else? 14 A. I mean since the Hammons 15 case I've read articles of literature, 16 background material that was sent to me 17 by Ethicon, did a pub med literature 18 search looking for different articles. 19 Q. Anything else? 20 A. Not that I recall. 21 Q. How long did you meet with 22 Ms. Graff yesterday? 23 A. About 9:00 to 5:00. 24 Q. And other than -- was anyone</p> | <p style="text-align: right;">Page 40</p> <p>1 Q. When were you first asked to 2 work on Prolift+M? 3 A. I was given the charts for a 4 specific patient case sometime in 5 December of 2015. I met with him prior 6 to giving my -- or preparing my expert 7 case specific report. 8 Q. And that's in the -- 9 A. That was February 29th, 10 2016. 11 Q. That's in the Gomez case? 12 A. That is in the Gomez case. 13 Q. So in December of 2015, you 14 were first approached to work on a case 15 specific expert report for the Gomez 16 case? 17 A. That is correct. 18 Q. At that time in December of 19 2015 did you receive materials that were 20 about Prolift+M as well or was it just 21 the medical and case specific files for 22 Ms. Gomez? 23 A. I don't recall exactly when 24 those thumb drives started to arrive, but</p> |
| <p style="text-align: right;">Page 39</p> <p>1 else in attendance at that meeting? 2 A. No. 3 Q. Was anyone on the phone? 4 A. No. 5 Q. Had you ever met Ms. Graff 6 before yesterday? 7 A. Never. 8 Q. Did you meet with or have 9 telephone calls with any other attorneys 10 about your expert work in this case? 11 A. Yes. 12 Q. Tell me about that. 13 A. I had contacts with Attorney 14 Paul Rosenblatt. 15 Q. And when was that? 16 A. We met I think the last week 17 of January of 2016. 18 Q. Where was that meeting? 19 A. That was here in York. 20 Q. And who was in attendance? 21 A. Just he and I. 22 Q. Is that when you were first 23 asked to work on the Prolift+M case? 24 A. No.</p> | <p style="text-align: right;">Page 41</p> <p>1 I think it was in 2016. The end of 2015 2 were more patient specific. At one point 3 they did start sending material on the 4 Prolift+M and videos and drawings on 5 TVT-O as well and that came through those 6 little thumb drives. 7 Q. And those came in January of 8 2016? 9 A. I think so, but I can't be a 10 hundred percent sure if some came at the 11 end of the year or not. 12 Q. And when did you issue your 13 expert report on Prolift+M and TVT-O? 14 A. I never issued an expert 15 report specifically for Prolift+M or 16 TVT-O. I issued a case report for the 17 Gomez case February 29th of 2016. 18 Q. And what do you mean by that 19 distinction that you just made that you 20 -- so is it your testimony that you've 21 never issued a general causation expert 22 report for Prolift+M? 23 A. You'd have to tell me what 24 your definition is of expert report for</p> |

| | |
|--|--|
| <p style="text-align: right;">Page 42</p> <p>1 Prolift+M and TVT-O. Since Mrs. Gomez 2 has had both, those are generally 3 included in my expert report, but you 4 didn't ask me about the Gomez report. 5 Q. Do you have any other 6 reports other than the Hammons report and 7 the Gomez report? 8 A. I do not. 9 Q. So you don't have an expert 10 report that discusses Prolift+M in 11 general? 12 A. I don't have an exclusive 13 report that only talks about Prolift+M. 14 Q. The portions of your report 15 in the Gomez case that talk about 16 Prolift+M, do you consider those to be a 17 complete opinion about the safety and 18 efficacy of the Prolift+M? 19 A. As complete as I can give at 20 this point in time. 21 Q. And what do you mean by 22 that? 23 A. That there are probably 500 24 articles, maybe more, in the literature</p> | <p style="text-align: right;">Page 44</p> <p>1 Q. When you said that it's as 2 complete an opinion as you can give at 3 this time, do you mean by that that at 4 this time because new literature is still 5 coming out that you haven't had a chance 6 to review it yet because it hasn't been 7 published? 8 A. That's a possibility. 9 Q. What else did you mean by 10 "at this time"?</p> <p>11 A. I think given more time 12 there may be other articles that are not 13 cited, but the major articles published 14 in the literature I've based my opinion 15 on plus my experience, so I would have to 16 agree it would have to come out in 17 unpublished literature not published yet. 18 Q. Are your opinions about the 19 Prolift+M as set forth in your Gomez 20 report, are those opinions applicable to 21 other patients other than Ms. Gomez as 22 far as the safety and efficacy of the 23 Prolift+M? 24 A. As far as the reported</p> |
| <p style="text-align: right;">Page 43</p> <p>1 on prolapse and use of mesh. The 2 literature gets added onto just about 3 every day, and so at this point in time 4 that's my best opinion on Prolift+M. 5 Q. Would you consider the 6 opinions that you provided in the Gomez 7 case concerning Prolift+M, would you 8 consider that you've had sufficient time 9 to do a thorough study of the Prolift+M? 10 MS. GRAFF: Object to form. 11 THE WITNESS: With my 12 experience and what I've read over 13 the years plus what I have read 14 over the last few months, I think 15 yes. 16 BY MR. ZONIES: 17 Q. Would you -- are you 18 confident that you have reviewed all of 19 the information that you need to have 20 reviewed to express your opinion to a 21 reasonable degree of medical certainty 22 about the safety and efficacy of the 23 Prolift+M device? 24 A. I do.</p> | <p style="text-align: right;">Page 45</p> <p>1 safety and efficacy, yes. 2 Q. Those opinions are not 3 specific to Ms. Gomez' case? 4 A. The general opinions that 5 are cited in my expert report concerning 6 Prolift+M and my review of literature are 7 specific to Prolift+M to a reasonable 8 degree of medical certainty. 9 Q. And what does that mean to 10 you, "reasonable degree of medical 11 certainty"?</p> <p>12 A. It means more likely than 13 not. 14 Q. Did you bring any materials 15 or documents with you today other than 16 the thumb drive you provided? 17 A. I did not bring the thumb 18 drive, Melissa Graff did, and I have this 19 box here of materials that were delivered 20 to me last Thursday. 21 Should I give them to him? 22 MS. GRAFF: Yeah. That's 23 fine. 24 Just for the record, what's</p> |

| Page 46 | Page 48 |
|---|--|
| <p>1 in those binders is what's on the 2 thumb drive.</p> <p>3 THE WITNESS: That was 4 delivered to me Thursday of last 5 week. Thursday afternoon.</p> <p>6 MR. ZONIES: I don't know 7 what we're going to do about 8 marking them.</p> <p>9 MS. GRAFF: So again, 10 everything in here is what's on 11 the thumb drive and she doesn't 12 have any notes, so you can flip 13 through it if you want to, but 14 they're the same.</p> <p>15 BY MR. ZONIES:</p> <p>16 Q. So it's your understanding, 17 Doctor, that what's in these two binders 18 is also what is on that thumb drive. Is 19 that fair to say?</p> <p>20 A. Not quite.</p> <p>21 Q. Go ahead and tell me your 22 understanding.</p> <p>23 A. I went through all of those 24 over the weekend and there are some</p> | <p>1 them on the thumb drive. That will be 2 the difference.</p> <p>3 MR. ZONIES: So why don't we 4 go ahead mark these as Exhibits 1 5 and 2 and the thumb drive as 6 Number 3.</p> <p>7 (Whereupon, the court 8 reporter marked Exhibits 1, 2 and 9 3 for identification as of this 10 date.)</p> <p>11 THE WITNESS: Some of these 12 --</p> <p>13 MS. GRAFF: Just a minute.</p> <p>14 BY MR. ZONIES:</p> <p>15 Q. So you were saying, Doctor? 16 Go ahead.</p> <p>17 A. Some of them have the 18 correct author, but that same author 19 published different articles in the same 20 year, and so there are one or two of them 21 that are not the correct articles cited 22 in my reference although it is the same 23 author and the same year. Just 24 different.</p> |
| <p>1 articles there that although have a title 2 are not the correct articles. This was 3 prepared by Butler Snow, it arrived from 4 Butler Snow, and what they took were my 5 references and plugged in the articles, 6 except there are three or four articles 7 in there that have nothing to do with 8 pelvic floor, wrong author, one of them 9 is on laparoscopic adrenalectomy, the 10 other one is on ovarian reserve after 11 laparoscopic salpingectomy, so I have, 12 good luck with that, I have informed Mrs. 13 Graff of this yesterday but I've also 14 informed Attorney Rosenblatt Sunday night 15 wee hours of Monday morning, I think it 16 was 12:04 when my email was sent to him 17 about the corrections that needed to be 18 made to this.</p> <p>19 Q. And when you say "this", 20 you're pointing to the binder?</p> <p>21 A. I am pointing to the binder.</p> <p>22 Subsequently, yesterday 23 Attorney Graff was able to get the 24 correct articles from Butler Snow and put</p> | <p>1 Q. Understood. So the two 2 binders that we've marked as Exhibits 1 3 and 2 are entitled Materials Referenced 4 in Drolet Report; is that right?</p> <p>5 A. Correct.</p> <p>6 Q. And are these -- did you 7 direct that these materials be gathered?</p> <p>8 A. I did not direct it, no.</p> <p>9 Q. Are these materials that are 10 cited in the body of your report?</p> <p>11 A. Most of them, yes. Some of 12 them, no. These are -- there's an expert 13 report here from Doctor Garely specific 14 to the Hammons case, depositions of 15 Doctor Albrecht. So some of them are in 16 my report, but there's a few here that 17 are not in my report, but these are the 18 binders that were sent to me and what I 19 was told to bring today.</p> <p>20 Q. And who told you to bring 21 them today?</p> <p>22 A. Attorney Graff.</p> <p>23 Q. I'm now holding Exhibit 2, 24 Materials Referenced in Drolet Report</p> |

| Page 50 | Page 52 |
|--|--|
| <p>1 Binder 2 of 2 and one of the tabs is 2 called Depos and CER; is that right? 3 A. That's what it says. 4 Q. And behind those tabs, 5 behind that tab are the 2015 Margolis CER 6 4/24/15. Is that what that tab says? 7 A. With my glasses from here, 8 yes, it absolutely looks like that. Yes. 9 Q. And can you tell me what is 10 that behind that tab? 11 A. It's the expert report of 12 Michael Thomas Margolis. 13 Q. In what case? 14 A. This is Ramirez Galindo, 15 Plaintiff. 16 Q. And have you ever read that 17 expert report? 18 A. That was sent to me. 19 Q. When? 20 A. Sometime this winter, so 21 between January 1st, 2016 up until 22 probably beginning of March. Sometime 23 like that. I'm not sure. 24 Q. Do you think it was sent to</p> | <p>1 A. Yes. I don't recall seeing 2 this at all. I don't remember Kari 3 Smith. So this was put in my binder that 4 was sent to me and I did not read this. 5 Q. You don't think you read 6 that in preparation for this deposition? 7 A. I'm convinced. I'm certain 8 I did not read this. 9 Q. Okay. Now that you've seen 10 that, if you look back at the Margolis 11 expert report we were just looking at, 12 that tab in Binder Number 2 is 2015 13 Margolis CER 4-24-15 for a case caption 14 that is Ramirez. Do you think that you 15 read that prior to your doing your report 16 in this case? 17 A. I don't think I have. That 18 I'm -- this one I'm not quite sure. 19 Q. Okay. May I? 20 A. Oh, absolutely. 21 Q. Thank you. 22 And then the last tab in 23 this second binder that's marked as 24 Exhibit 2 is the tab says Prolift -</p> |
| <p>1 you prior to your issuing your expert 2 report in the Gomez case? 3 A. That one I'm not sure. 4 Q. Okay. What about the next 5 one? What is the title on the next tab? 6 A. The next tab is 2016 7 Albrecht -- A-L-B-R-E-C-H-T -- 8 2016-02-08. That I received before my 9 report. 10 Ostergard, Donald, expert 11 report. 12 Q. And you're looking at a tab 13 now that's -- what's the case name on the 14 top of that document? 15 A. Is that -- is this here? 16 Q. Yes. 17 A. This is Kari Smith v. 18 Ethicon. 19 Q. When do you think you 20 received that report from Doctor 21 Ostergard? 22 A. I think I got this last 23 Thursday. 24 Q. For the first time?</p> | <p>1 Page 51 1 Garely -- G-A-R-E-L-Y -- and I'm going to 2 hand that to you and ask you if you've 3 read that prior to doing your report in 4 this case. 5 A. I'll have to read it all to 6 remind myself just to be sure, but I do 7 recall a general report and a Doctor 8 Garely. Is it the same physician? I'm 9 not sure because I don't recall seeing 10 pictures, so I don't think I've read 11 this. 12 Q. Okay. May I have that 13 binder back, Doctor? 14 A. Yes, you certainly may. 15 Q. Thank you. 16 MS. GRAFF: We've been going 17 for about an hour, Counsel. Is 18 there a time when we can take a 19 break? 20 MR. ZONIES: Any time. Why 21 don't we go ahead and take a 22 break? 23 (Whereupon, a brief recess 24 was held from 11:10 a.m. to 11:18</p> |

| Page 54 | Page 56 |
|---|--|
| <p>1 a.m.)</p> <p>2 BY MR. ZONIES:</p> <p>3 Q. Doctor, after a break, are</p> <p>4 you ready to go?</p> <p>5 A. I am.</p> <p>6 Q. Did you bring with you today</p> <p>7 any invoices for the work you've done on</p> <p>8 this expert report?</p> <p>9 A. I did not.</p> <p>10 MS. GRAFF: I think it's on</p> <p>11 the thumb drive.</p> <p>12 THE WITNESS: It's on the</p> <p>13 thumb drive.</p> <p>14 MR. BENTLEY: Maybe.</p> <p>15 BY MR. ZONIES:</p> <p>16 Q. In addition to the invoices</p> <p>17 and copies of some of the documents in</p> <p>18 Binders 1 and 2 and the corrected studies</p> <p>19 for what you intended to be in Binders 1</p> <p>20 and 2, is there anything else on that</p> <p>21 thumb drive?</p> <p>22 A. I would not know. I've not</p> <p>23 seen the thumb drive. I wasn't privy to</p> <p>24 it. I think -- I don't know when my</p> | <p>1 on the thumb drive?</p> <p>2 A. I have not seen the thumb</p> <p>3 drive. It arrived to Attorney Graff, in</p> <p>4 Attorney Graff's possession after we had</p> <p>5 met.</p> <p>6 Q. So the answer is, no, you</p> <p>7 don't know that the thumb drive actually</p> <p>8 contains the correct materials either?</p> <p>9 A. The corrected materials were</p> <p>10 added on this morning by Attorney Graff</p> <p>11 and I did see that she did add on those</p> <p>12 articles.</p> <p>13 Q. And this morning did you</p> <p>14 notice if was anything deleted off of the</p> <p>15 thumb drive or were the incorrect ones</p> <p>16 also left on there?</p> <p>17 A. I don't exactly have any</p> <p>18 confirmation of that one way or the</p> <p>19 other.</p> <p>20 Q. And in making those</p> <p>21 corrections to the materials that were in</p> <p>22 these binders, did you focus only on the</p> <p>23 scientific studies?</p> <p>24 A. I mostly did, yes.</p> |
| <p>1 attorney received it. I have no idea.</p> <p>2 Q. Right.</p> <p>3 MS. GRAFF: I received it</p> <p>4 yesterday after I met with her, so</p> <p>5 she has not seen it.</p> <p>6 BY MR. ZONIES:</p> <p>7 Q. You said that you went</p> <p>8 through these binders when you received</p> <p>9 them on Thursday; correct?</p> <p>10 A. I said I received them on</p> <p>11 Thursday and I went through them over the</p> <p>12 weekend.</p> <p>13 Q. And while going through the</p> <p>14 binders you identified some errors in the</p> <p>15 scientific articles that were included in</p> <p>16 these binders as compared to what you</p> <p>17 intended to be included in the binders.</p> <p>18 Is that fair?</p> <p>19 A. They were not the correctly</p> <p>20 cited articles. I did not read through</p> <p>21 those incorrect articles.</p> <p>22 Q. Have you had a chance to</p> <p>23 review the thumb drive to ensure that the</p> <p>24 corrected versions of those articles are</p> | <p>1 Q. So we were just looking at,</p> <p>2 for example, a number of expert reports</p> <p>3 from Plaintiff's experts that appear they</p> <p>4 also may be incorrect but you didn't</p> <p>5 review those to notice that they were</p> <p>6 incorrect; correct?</p> <p>7 A. I don't know if I would</p> <p>8 characterize them as incorrect, but those</p> <p>9 are materials that I may not or would not</p> <p>10 have viewed in order to prepare my expert</p> <p>11 report.</p> <p>12 Q. Understood. So I have what</p> <p>13 I believe to be a copy of your expert</p> <p>14 report. Did you bring a copy of your</p> <p>15 expert report with you today?</p> <p>16 A. I did not, but it's in the</p> <p>17 binder.</p> <p>18 Q. Great. Thank you.</p> <p>19 So in the Exhibit 1 entitled</p> <p>20 Materials Referenced in Drolet Report</p> <p>21 Binder 1 of 2, you have in the first tab</p> <p>22 the Drolet Case Specific Gomez is what it</p> <p>23 states. Would this be your expert report</p> <p>24 in this case?</p> |

| | |
|---|--|
| <p style="text-align: right;">Page 58</p> <p>1 A. That would be. 2 Q. This would be your expert 3 report about the safety and efficacy of 4 Prolift+M; is that correct? 5 A. That would be included in 6 the Gomez report because she had 7 Prolift+M along with TTV-O. 8 Q. Doctor, I'm going to go 9 ahead and we'll replace this first tab 10 into the binder after we finish, but I'll 11 go ahead and mark as Exhibit 4 the first 12 tab from Exhibit 1. 13 MR. ZONIES: Should we call 14 it 1-A? What would you prefer? 15 Why don't we call this 1-A 16 then? I'll correct that on the 17 record. 18 (Whereupon, the court 19 reporter marked Exhibit 1-A for 20 identification as of this date.) 21 MR. ZONIES: I misspoke. 22 What we've marked as Exhibit 1-A 23 is the first tab in Binder 1 which 24 is Exhibit 1.</p> | <p style="text-align: right;">Page 60</p> <p>1 A. Yes. It was after midnight. 2 Q. After midnight of? 3 A. Well, from the February 4 29th -- 5 Q. Yes. 6 A. -- to March 1st. 7 Q. So you signed it on March 8 1st, but it was in the early hours of 9 March 1st. Is that fair? 10 A. Kind of sort of. 11 Q. What do you mean? 12 A. The whole report was 13 finished on February 29th of 2016 before 14 midnight, but I did not have the 15 capability of scanning a signed 16 signature. So the whole report was sent 17 and then Butler Snow had it in their 18 possession and the next morning they said 19 scan it when you get to the office with 20 your signature and we'll add to it. 21 Q. Understood. 22 A. That's why the dates are 23 different. I didn't put this date. They 24 did.</p> |
| <p style="text-align: right;">Page 59</p> <p>1 BY MR. ZONIES: 2 Q. Is this your expert report 3 on Prolift+M? 4 A. It is my expert report in 5 the case of the Rose Gomez case. 6 Q. And that includes your 7 opinions on the safety and efficacy of 8 Prolift+M; correct? 9 A. That would be correct. 10 Q. You issued a reliance list 11 with your report. Do you have a copy of 12 that reliance list with you today? 13 A. I do not. 14 Q. Doctor, can you look at that 15 report on the last page? I believe you 16 signed it on the last page. Is that 17 right? 18 A. That is correct. 19 Q. And what is the date of your 20 signature? 21 A. That date is March 1st, 22 2016. 23 Q. And is that when you 24 actually signed that document?</p> | <p style="text-align: right;">Page 61</p> <p>1 Q. So you had completed the 2 report and sent it to the attorneys at 3 Butler Snow unsigned? 4 A. That would be correct 5 because I don't have the capacity to sign 6 on my computer. 7 Q. And then you subsequently 8 executed the signature page with the 9 March date on it and scanned and emailed 10 that to Butler Snow? 11 A. That would be correct. 12 Q. When you signed it and 13 emailed it on March 1st, did you just 14 review that single page or did you review 15 the entire report one more time? 16 A. Only the back of the last 17 page. That back page was sent like this. 18 Q. Okay. So you didn't have a 19 chance to review the entire report prior 20 to sending your signature? 21 A. It wasn't sent back to me, 22 no. 23 Q. Doctor, I'm going to hand 24 you -- have marked and hand you Exhibit</p> |

| | |
|--|---|
| <p>1 Number 4.</p> <p>2 (Whereupon, the court</p> <p>3 reporter marked Exhibit 4 for</p> <p>4 identification as of this date.)</p> <p>5 BY MR. ZONIES:</p> <p>6 Q. Doctor, do you have Exhibit</p> <p>7 Number 4 in front of you?</p> <p>8 A. Yes, I do.</p> <p>9 Q. And what is Exhibit Number</p> <p>10 4?</p> <p>11 A. It says Reliance List in</p> <p>12 Addition to Materials Referenced in</p> <p>13 Report, Rose Gomez.</p> <p>14 Q. And have you seen this</p> <p>15 document before?</p> <p>16 A. I've seen a document like</p> <p>17 this yesterday afternoon while meeting</p> <p>18 with Attorney Graff.</p> <p>19 Q. And was that the first time</p> <p>20 you saw this document?</p> <p>21 A. Yes, it was.</p> <p>22 Q. You didn't actually prepare</p> <p>23 this document?</p> <p>24 A. I did not type this</p> | <p>Page 62</p> <p>1 document? Correct?</p> <p>2 A. That would be correct. The</p> <p>3 typed form of this document. Right.</p> <p>4 Q. And as you can see, the</p> <p>5 first 14 pages of this document is</p> <p>6 entitled Medical Literature; is that</p> <p>7 correct?</p> <p>8 A. That would be correct,</p> <p>9 excluding the first page, the title page.</p> <p>10 Q. And as we're sitting here</p> <p>11 today, do you have any way of knowing</p> <p>12 which of these studies you actually</p> <p>13 reviewed prior to creating your expert</p> <p>14 report? Strike that.</p> <p>15 As we're sitting here today,</p> <p>16 Doctor, do you any way of knowing absent</p> <p>17 going through each piece of literature</p> <p>18 one by one which of these you actually</p> <p>19 reviewed and relied upon in the</p> <p>20 preparation of your expert report in this</p> <p>21 case?</p> <p>22 MS. GRAFF: Object to form.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: I would say</p> |
| <p>1 document. That is correct.</p> <p>2 Q. And yesterday when you went</p> <p>3 through this document, did you find any</p> <p>4 concerns or mistakes in this document?</p> <p>5 A. I did have some things that</p> <p>6 I wasn't quite sure I had read.</p> <p>7 Q. Okay. Such as?</p> <p>8 A. Well, I'd have to go through</p> <p>9 it, or referenced, and I don't know if</p> <p>10 this is the same copy of what I saw</p> <p>11 yesterday.</p> <p>12 Q. Understood.</p> <p>13 A. When did you receive this?</p> <p>14 Q. If you see up at the top, it</p> <p>15 says 2/29/2016. Do you see that?</p> <p>16 A. Yes, I see that.</p> <p>17 Q. That's when. It was issued</p> <p>18 with your report.</p> <p>19 A. Okay. So I did not know if</p> <p>20 that's when you --</p> <p>21 Q. So would it be fair to say,</p> <p>22 Doctor, that certainly as of 2/29/2016,</p> <p>23 the date on the top of this and when your</p> <p>24 report was issued you had not seen this</p> | <p>Page 63</p> <p>1 the vast majority.</p> <p>2 BY MR. ZONIES:</p> <p>3 Q. The vast majority of what?</p> <p>4 A. Of all of these articles.</p> <p>5 Q. So for example, there's an</p> <p>6 article by Waltregny in this reliance</p> <p>7 list. Do you think you read that</p> <p>8 article?</p> <p>9 A. I haven't gone through it</p> <p>10 yet.</p> <p>11 MS. GRAFF: There's actually</p> <p>12 two.</p> <p>13 THE WITNESS: There are two</p> <p>14 on there. I'm not quite sure</p> <p>15 which one of those.</p> <p>16 BY MR. ZONIES:</p> <p>17 Q. Do you think you reviewed</p> <p>18 either of those?</p> <p>19 A. I can't recall at a hundred</p> <p>20 percent that I have for the preparation</p> <p>21 of this case.</p> <p>22 Q. Understood. Well, those</p> <p>23 are, for example, those are Waltregny</p> <p>24 documents --</p> |

| Page 66 | Page 68 |
|--|--|
| <p>1 A. Actually, I have -- let me 2 rephrase this. I have definitely the one 3 with deLeval, the 2009, yes.</p> <p>4 Q. You think you have reviewed 5 that one?</p> <p>6 A. I have reviewed it.</p> <p>7 Q. That's not a journal that 8 you subscribe to I assume, "The 9 International Urogynecologic Journal"?</p> <p>10 A. I do not. It's the 11 "International Urogynecological Journal 12 of Pelvic Floor Dysfunction", but part of 13 the pub med list of articles that I 14 periodically submitted to Butler Snow so 15 that they could send me the articles.</p> <p>16 Q. And do you know how the 17 articles were chosen to be put on this 18 medical literature reliance list?</p> <p>19 A. Some of these are probably 20 derived from my first reliance list for 21 the Hammons case.</p> <p>22 Q. Okay.</p> <p>23 A. And some of these articles, 24 a lot of them or a portion of them I have</p> | <p>1 nomenclature in the thumb drives so 2 there's no way for me to currently as we 3 speak now be a hundred percent sure that 4 the cross reference was made. I was not 5 sent anything in any type of order or 6 alphabetical order or numerical order, 7 and so this is the list that they have 8 given me.</p> <p>9 Q. And you said that you would 10 have received these items on a thumb 11 drive; is that right?</p> <p>12 A. That is correct. The 13 experts' reports here that are on the 14 last few pages --</p> <p>15 Q. Yes.</p> <p>16 A. -- the Blaivas, Jerry, 17 Prolift report, TVT Abbrevio, Exact, all 18 these I've not seen. I am not quite sure 19 if I have received the expert report from 20 Doctor Elliott either.</p> <p>21 Q. So you're looking on the --</p> <p>22 A. They're not numbered. The 23 third to last page.</p> <p>24 Q. -- third to last page of</p> |
| <p>1 asked for those articles from Butler Snow 2 and they said they would add them onto my 3 reliance list. That's how Attorney 4 Rosenblatt said he would do it.</p> <p>5 Q. Okay. And after the section 6 on medical literature, there's a section 7 called document description or it's 8 actually called Production Materials. Do 9 you see that section?</p> <p>10 A. Yes.</p> <p>11 Q. What's your understanding of 12 what that means, Production Materials?</p> <p>13 A. Those are materials that 14 were produced by Ethicon, internal 15 documents, anatomy video.</p> <p>16 Q. In looking at this list here 17 as you're sitting here today, do you 18 believe that you've reviewed all of these 19 documents?</p> <p>20 A. Most of them, yes. Some of 21 them I can't make the cross reference. 22 As an example, anatomy video Ethicon, 23 ETH-MESH-PM000006 versus the 000009, 24 those things were not included as far as</p> | <p>1 Exhibit 4, your reliance materials where 2 it lists at the top it says 3 depositions --</p> <p>4 A. Yes.</p> <p>5 Q. -- and then it says Expert 6 Reports; correct?</p> <p>7 A. Correct.</p> <p>8 Q. And under Expert Reports, it 9 says there are six expert reports listed 10 for Doctor Blaivas; correct?</p> <p>11 A. That's correct. I don't 12 believe I've read any of those.</p> <p>13 Q. Okay. And that includes his 14 Prolift report and his TVT-O report; 15 correct?</p> <p>16 A. That's correct.</p> <p>17 Q. You haven't read those; 18 correct?</p> <p>19 A. That would be correct.</p> <p>20 Q. And then there's four expert 21 reports from Doctor Elliott including a 22 Prolift and a TVT-O; correct?</p> <p>23 A. Correct.</p> <p>24 Q. And it's your recollection</p> |

| Page 70 | Page 72 |
|--|---|
| <p>1 that you have not reviewed those either?</p> <p>2 A. Not the TVT, TTVT-O and</p> <p>3 TTVT-S. I'm not quite about the Prolift</p> <p>4 general, if that wasn't provided to me in</p> <p>5 the previous case because it was a</p> <p>6 Prolift case, that could have been</p> <p>7 provided to me by the Hammons case, but</p> <p>8 it's not something that I reviewed for</p> <p>9 this case here, the Gomez case.</p> <p>10 Q. How about the Garely</p> <p>11 Prolift+M general report? Have you ever</p> <p>12 reviewed that?</p> <p>13 A. I think that was sent to me</p> <p>14 for this case, the Margolis report</p> <p>15 possibly, the Ostergard report, yes. The</p> <p>16 Rosenzweig five reports on Prosima, TTVT</p> <p>17 and TTVT-O I have not received those, did</p> <p>18 not read.</p> <p>19 Q. So the Garely Prolift+M</p> <p>20 general report that has a date next to it</p> <p>21 of February 1st, 2016, it's your belief</p> <p>22 that you may have reviewed that expert</p> <p>23 report?</p> <p>24 A. I may have. I'm just not a</p> | <p>1 Certificate of Service here of February</p> <p>2 1st, 2016, so that may be. It just</p> <p>3 doesn't look familiar. I'm sorry.</p> <p>4 Q. As you sit here, you don't</p> <p>5 have any specific recollection of having</p> <p>6 reviewed Doctor Garely's Prolift+M</p> <p>7 report?</p> <p>8 A. Not looking at these</p> <p>9 pictures.</p> <p>10 Q. Do you recall as you're</p> <p>11 sitting here today, Doctor, having</p> <p>12 reviewed any Plaintiff's expert report on</p> <p>13 the Prolift+M?</p> <p>14 A. No, I don't have any</p> <p>15 specific recollection.</p> <p>16 Q. On Exhibit 4, at the top of</p> <p>17 the page we were just on on Exhibit 4,</p> <p>18 the reliance list exhibit, do you have</p> <p>19 that in front of you?</p> <p>20 A. I have the reliance list.</p> <p>21 Q. Good. It says depositions.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And there are three</p> |
| <p>1 hundred percent sure.</p> <p>2 Q. And if we look in the</p> <p>3 binders that you've brought with you</p> <p>4 today, that report is not in the binders</p> <p>5 that you provided in Exhibits 1 and 2?</p> <p>6 A. Somebody would have to check</p> <p>7 to be sure. Or is it?</p> <p>8 Q. Doctor, I'm going to go</p> <p>9 ahead and hand you Exhibit 2 which is the</p> <p>10 second binder of materials that you</p> <p>11 brought with you today and the last tab</p> <p>12 is actually an expert report from Doctor</p> <p>13 Garely but it's entitled I think Prolift;</p> <p>14 is that right?</p> <p>15 A. That's correct.</p> <p>16 Q. And that's not a Prolift+M</p> <p>17 expert report from your quick review?</p> <p>18 A. From the title it says</p> <p>19 Prolift.</p> <p>20 Q. So do you think that you</p> <p>21 reviewed Doctor Garely's Prolift report</p> <p>22 that you're looking at now?</p> <p>23 A. When was this issued? Do we</p> <p>24 have a date on this? I have a</p> | <p>1 depositions listed there?</p> <p>2 A. Yes.</p> <p>3 Q. Do you recall reviewing any</p> <p>4 -- do you recall reviewing those three</p> <p>5 depositions first of all?</p> <p>6 A. I do.</p> <p>7 Q. Did you review any other</p> <p>8 depositions in the preparation of this</p> <p>9 report?</p> <p>10 A. In the preparation of this</p> <p>11 report, no, not for this report.</p> <p>12 Q. Did you -- have you reviewed</p> <p>13 any of the depositions of any of the</p> <p>14 Plaintiff's experts related to the</p> <p>15 Prosima+M or the TTVT-O?</p> <p>16 A. No Prosima+M.</p> <p>17 Q. We can leave it at that.</p> <p>18 I'll ask you about the TTVT-O this</p> <p>19 afternoon.</p> <p>20 A. Okay.</p> <p>21 Q. Since your deposition in the</p> <p>22 Hammons case, have you published any</p> <p>23 articles in any peer review papers?</p> <p>24 A. I have not.</p> |

| Page 74 | Page 76 |
|---|--|
| <p>1 Q. How many -- how much -- I 2 don't think we've been able to crack that 3 thumb drive yet, but do you know how much 4 your total billing has been for the 5 creation of this report and the 6 preparation for your deposition today?</p> <p>7 A. I don't have a specific 8 number.</p> <p>9 Q. Do you have an estimate, or 10 no?</p> <p>11 A. Total number?</p> <p>12 MS. GRAFF: I'm sorry. I 13 was talking to your colleague. 14 You're asking how many hours was 15 the question?</p> <p>16 MR. ZONIES: Yes. How many 17 hours.</p> <p>18 THE WITNESS: Over 100 19 hours, 120 hours.</p> <p>20 BY MR. ZONIES:</p> <p>21 Q. So between the time in 22 December of 2015 when you were approached 23 to work on this report and today, you've 24 spent over 120 hours?</p> | <p>1 so the overall polypropylene included in 2 the Prolift+M is less than in the 3 Prolift. I believed it was an evolution 4 to go back to your previous question, an 5 evolution in the product and they came 6 out with Prolift+M and used it.</p> <p>7 Q. You didn't have any, or as 8 you sit here today you don't recall any 9 specific scientific or medical reason 10 that you felt that the Prolift+M would be 11 a better device to use than the Prolift?</p> <p>12 A. Specifically at the time, 13 no.</p> <p>14 Q. Did you believe that having 15 less mesh left in the pelvic floor due to 16 resorption would somehow be better?</p> <p>17 A. That's I think what was the 18 idea at the time, that we would try to 19 make better, thinner meshes, and if we 20 could decrease the load and have a 21 resorbable component to it would be 22 improving.</p> <p>23 Q. And you're saying that that 24 was the idea at the time?</p> |
| <p>1 A. Probably.</p> <p>2 Q. How much of that -- well, I 3 think we may have the invoices so I'll 4 try to get that on a break.</p> <p>5 MR. ZONIES: Why don't we go 6 ahead and take a break? How is 7 that? Why don't we find out 8 what's on there?</p> <p>9 (Whereupon, a brief recess 10 was held from 11:45 a.m. to 11:50 11 a.m.)</p> <p>12 BY MR. ZONIES:</p> <p>13 Q. Doctor, why did you make the 14 change from Prolift to Prolift+M?</p> <p>15 A. I don't specifically recall.</p> <p>16 Q. Did you believe that there 17 was some benefit with the Prolift+M over 18 and above the Prolift?</p> <p>19 A. I'm not quite sure. Can't 20 answer you.</p> <p>21 Q. How would you describe the 22 difference between Prolift and Prolift+M?</p> <p>23 A. Prolift+M contains a weave 24 of Monocryl which resorbs into the body,</p> | <p>1 A. Uh-huh.</p> <p>2 Q. By that do you mean that's 3 what Ethicon was saying at the time about 4 Prolift+M is that it would have a reduced 5 mesh load because of resorption?</p> <p>6 MS. GRAFF: Object to form.</p> <p>7 THE WITNESS: I don't know 8 if it was just Ethicon. I think a 9 lot of companies were looking for 10 ways to improve products, their 11 own products, so that was a school 12 of thought.</p> <p>13 BY MR. ZONIES:</p> <p>14 Q. And was that your belief at 15 the time that the Prolift+M because it 16 would have a lower mesh load due to the 17 resorption portion of the mesh, that that 18 would somehow have clinical benefit for 19 your patients?</p> <p>20 A. That was one I think reason.</p> <p>21 Q. Was it the primary reason?</p> <p>22 A. I'm not quite sure at the 23 time.</p> <p>24 Q. How about as you sit here</p> |

| | |
|---|--|
| <p>1 today?</p> <p>2 A. I think it's not just mesh</p> <p>3 load or the weight of the mesh. It's a</p> <p>4 combination of multiple factors.</p> <p>5 Q. And what do you mean by "it"</p> <p>6 is, "it's a combination of multiple</p> <p>7 factors"? What is?</p> <p>8 A. As far as being a, to use</p> <p>9 your term, better product, better, slash,</p> <p>10 different.</p> <p>11 Q. What do you understand the</p> <p>12 differences to be between the Prolift kit</p> <p>13 and the Prolift+M kit other than --</p> <p>14 clearly one difference you've described</p> <p>15 is the difference in the mesh itself with</p> <p>16 a portion of it being resorbable;</p> <p>17 correct?</p> <p>18 A. That would be correct.</p> <p>19 Q. Any other differences?</p> <p>20 A. I'm not sure if the shape of</p> <p>21 the introducer had changed or not. I</p> <p>22 can't recall.</p> <p>23 Q. As you sit here today, do</p> <p>24 you know if the shape of the introducer</p> | <p>Page 78</p> <p>1 opinion in my experience.</p> <p>2 Q. Were they at a more acute</p> <p>3 angle?</p> <p>4 A. I can't tell. You're asking</p> <p>5 me.</p> <p>6 Q. So you don't know if they</p> <p>7 were or were not?</p> <p>8 A. As we sit today, I don't</p> <p>9 recall.</p> <p>10 Q. Do you know if the, prior to</p> <p>11 the Prolift+M being sold, whether or not</p> <p>12 a polypropylene Monocryl combined mesh</p> <p>13 had ever been used in the pelvic floor?</p> <p>14 A. It was called ULTAPRO, but I</p> <p>15 don't know if it was sold in another kit</p> <p>16 or something.</p> <p>17 Q. The mesh itself that was</p> <p>18 used in the Prolift+M was called</p> <p>19 ULTRAPRO; is that right?</p> <p>20 A. Yes.</p> <p>21 Q. Do you believe that Ethicon</p> <p>22 -- strike that.</p> <p>23 Were you told by anyone at</p> <p>24 Ethicon that there had been testing on</p> |
| <p>1 changed?</p> <p>2 A. I can't recall.</p> <p>3 Q. Was the procedure the same?</p> <p>4 A. It didn't seem any different</p> <p>5 to me in my experience. You still had to</p> <p>6 put it along the arcus tendineus fasciae</p> <p>7 pelvis for an anterior Prolift, you still</p> <p>8 had to put it through the sacrospinous</p> <p>9 ligament for a total or posterior</p> <p>10 Prolift+M, so the procedure itself did</p> <p>11 not change.</p> <p>12 Q. Do you know if the shape of</p> <p>13 the mesh itself changed in any way?</p> <p>14 A. I did not notice a</p> <p>15 significant change and I have not seen</p> <p>16 them side to side to be able to take</p> <p>17 precise measurements.</p> <p>18 Q. So you don't have a sense</p> <p>19 that, for example, the shape of the arms</p> <p>20 changed in any way?</p> <p>21 A. If they were less of an</p> <p>22 acute or more of an acute angle in</p> <p>23 relationship to the body of the mesh, it</p> <p>24 didn't make any clinical difference in my</p> | <p>Page 79</p> <p>1 the ULTRAPRO mesh in the pelvic floor</p> <p>2 that showed that it had better outcomes</p> <p>3 because of a reduced mesh load?</p> <p>4 A. I'm not sure if I had heard</p> <p>5 that through Ethicon or not.</p> <p>6 Q. Was that your belief at the</p> <p>7 time?</p> <p>8 A. Yes, I think it was.</p> <p>9 Q. Did you -- were you shown</p> <p>10 any testing that would demonstrate that</p> <p>11 to be true at the time?</p> <p>12 A. I don't recall.</p> <p>13 Q. Would you expect a</p> <p>14 reasonable medical device company to have</p> <p>15 testing that would demonstrate that the</p> <p>16 Prolift+M was somehow a better product</p> <p>17 than the Prolift?</p> <p>18 MS. GRAFF: Object to form.</p> <p>19 BY MR. ZONIES:</p> <p>20 Q. Prior to selling it.</p> <p>21 MS. GRAFF: Same objection.</p> <p>22 THE WITNESS: Well, I don't</p> <p>23 know what their rules are for</p> <p>24 going from Prolift to Prolift+M,</p> |

| | |
|--|---|
| <p style="text-align: right;">Page 82</p> <p>1 but I do believe it was cleared by 2 the FDA and so I did not have any 3 reason to disbelieve what they 4 would tell me.</p> <p>5 BY MR. ZONIES:</p> <p>6 Q. And did you believe that 7 there was, when you first started to use 8 Prolift+M, did you believe that there was 9 scientific support for the notion that 10 having some resorbable mesh would somehow 11 improve outcomes for your patients?</p> <p>12 A. It depends.</p> <p>13 Q. What do you mean?</p> <p>14 A. Well, Vypro also has a 15 resorbable component to it and I remember 16 reading something that, I think it was 17 Professor Jacquetin didn't like the 18 Vypro, so it's not a question of a 19 general resorbable component. It 20 depends.</p> <p>21 Q. What does it depend on?</p> <p>22 A. Well, there's a difference 23 between Vicryl and Monocryl. Vicryl is a 24 multifilament braided, so it depends on</p> | <p style="text-align: right;">Page 84</p> <p>1 difference.</p> <p>2 Q. Did you inform your patients 3 when you switched over to Prolift+M that 4 there was an absorbable component to 5 Prolift+M?</p> <p>6 A. I think I did.</p> <p>7 Q. And why would you tell them 8 that?</p> <p>9 A. I think I mentioned, or to 10 the best of my recollection I mentioned 11 it was mostly permanent but part it was 12 resorbable.</p> <p>13 Q. And did you describe that as 14 a benefit to the patient?</p> <p>15 A. I think -- or let me 16 rephrase this. I think -- no. When I 17 consent my patients, I tell them this is 18 what we're going to do, we're putting a 19 permanent mesh, part of it it will be 20 dissolvable, most of it stays permanent. 21 I did not distinguish risk benefits 22 versus something else that I wasn't using 23 at the time.</p> <p>24 Q. Would you have expected</p> |
| <p style="text-align: right;">Page 83</p> <p>1 multiple factors. So it's not just 2 having something resorbable. The mesh 3 that I used that had this collagen 4 overlay did not perform well and so that 5 collagen is absorbable.</p> <p>6 Q. So prior to using the 7 Prolift+M device, did you do any sort of 8 a risk benefit analysis of whether or not 9 you should switch to the Prolift+M from 10 Prolift?</p> <p>11 A. I did not conduct a risk 12 analysis study.</p> <p>13 Q. Did you just for your own 14 practice and your own discussions with 15 your patients, did you have some sort of 16 a risk benefit analysis of the 17 differences between the Prolift and the 18 Prolift+M?</p> <p>19 A. At the time, no, I did not.</p> <p>20 Q. Did you consent your 21 patients differently between the time 22 that you used Prolift and started to use 23 Prolift+M?</p> <p>24 A. Not in any significant</p> | <p style="text-align: right;">Page 85</p> <p>1 Ethicon to have done some clinical tests 2 using the Prolift+M prior to selling it 3 to you?</p> <p>4 A. It depends on what you say 5 tests. What do you mean by testing?</p> <p>6 Q. Would you have expected 7 Ethicon to have performed a clinical 8 trial with the Prolift+M before they sold 9 it to you?</p> <p>10 MS. GRAFF: Object to form.</p> <p>11 THE WITNESS: It depends on 12 the type of clinical trial.</p> <p>13 BY MR. ZONIES:</p> <p>14 Q. A clinical trial showing 15 even short-term outcomes associated with 16 the Prolift+M?</p> <p>17 MS. GRAFF: Same objection.</p> <p>18 THE WITNESS: I don't know 19 what I would have expected. I 20 think Doctor Lucente was still -- 21 was using it up in Allentown and 22 he had moved to it, so I used 23 Prolift+M.</p> <p>24 BY MR. ZONIES:</p> |

| | |
|--|--|
| <p style="text-align: right;">Page 86</p> <p>1 Q. So one of the things that 2 gave you comfort in moving to the 3 Prolift+M was that Doctor Lucente had 4 made the move from Prolift to Prolift+M?</p> <p>5 A. I think that's what I was 6 told.</p> <p>7 Q. By whom?</p> <p>8 A. I can't recall.</p> <p>9 Q. An Ethicon sales rep?</p> <p>10 A. I can't recall.</p> <p>11 Q. Would you have expected 12 Ethicon to have done some animal testing 13 with the Prolift+M mesh demonstrating 14 that it was in some way better than the 15 Prolift mesh?</p> <p>16 MS. GRAFF: Object to form.</p> <p>17 THE WITNESS: I did not know 18 or do not know what was required 19 at the time in order to go from 20 Prolift to Prolift+M, so I did not 21 have those expectations.</p> <p>22 BY MR. ZONIES:</p> <p>23 Q. Have you reviewed any 24 internal Ethicon documents discussing</p> | <p style="text-align: right;">Page 88</p> <p>1 A. If women had been treated 2 with Prolift and now there were studies 3 on ULTRAPRO that showed that it had a 4 benefit over the Gynemesh in general and 5 the FDA cleared it to be part of Prolift 6 now called Prolift+M, then if the FDA 7 cleared it, then it was going to be safe.</p> <p>8 Q. Is it your understanding as 9 a practicing physician and as an expert 10 witness in this case that if the FDA 11 clears a device for marketing that the 12 FDA has determined that it is safe and 13 effective?</p> <p>14 MS. GRAFF: Object to form, 15 but you can answer.</p> <p>16 THE WITNESS: Can you repeat 17 that question verbatim please?</p> <p>18 BY MR. ZONIES:</p> <p>19 Q. Sure. Is it your 20 understanding as a treating physician and 21 as an expert witness in this case that if 22 the FDA has cleared a medical device for 23 marketing under the 510(k) process that 24 the FDA has made a determination that</p> |
| <p style="text-align: right;">Page 87</p> <p>1 whether or not Ethicon should perform 2 animal testing prior to selling the 3 Prolift+M?</p> <p>4 A. I don't recall specifically 5 reading that.</p> <p>6 Q. Have you reviewed any 7 internal Ethicon documents demonstrating 8 Ethicon's discussions about whether or 9 not to perform a clinical trial in women 10 using the Prolift+M prior to selling the 11 device?</p> <p>12 A. I don't recall reading 13 something specifically to that effect.</p> <p>14 Q. If you had seen internal 15 Ethicon documents describing Ethicon's 16 choices not to perform animal testing 17 prior to marketing the device, would that 18 have been helpful in formulating your 19 opinion about whether or not this was a 20 safe and effective device?</p> <p>21 MS. GRAFF: Object to form.</p> <p>22 THE WITNESS: It depends.</p> <p>23 BY MR. ZONIES:</p> <p>24 Q. On what?</p> | <p style="text-align: right;">Page 89</p> <p>1 that device is safe and effective for its 2 intended use?</p> <p>3 A. At the time that they 4 cleared it, I would say yes.</p> <p>5 Q. Do you know what a 522 study 6 is?</p> <p>7 A. It is my understanding that 8 it is a postmarket study after a product 9 has been cleared by a 510(k) process.</p> <p>10 Q. Do you have an opinion, 11 Doctor, whether or not there is more or 12 less contraction with the Prolift+M as 13 compared to the Prolift?</p> <p>14 A. At this time the studies are 15 not well comparable in a sense that 16 there's no randomized control study 17 comparing Prolift and Prolift+M with a 18 sufficient amount of power and long 19 enough follow-up, but there does seem 20 that there may be slightly less in 21 comparing the studies that have been 22 published looking at the first years of 23 Prolift versus looking at patients who 24 have been implanted more recently, but</p> |

| Page 90 | Page 92 |
|--|---|
| <p>1 there are other confounding factors that 2 may alter those results. 3 Q. Would it have been helpful 4 to you as a treating physician when 5 making the decision to switch from 6 Prolift to Prolift+M to actually see 7 clinical trial data comparing the Prolift 8 and the Prolift+M? 9 A. It depends. In an ideal 10 world, you know, we'd love to wait for 11 all the studies to come out, but in 12 reality if we have something better, 13 maybe, possibly, or an improvement, 14 technological improvement and it has been 15 cleared by the FDA and it doesn't show 16 it's not an inferior product, then my 17 opinion is yes. 18 Q. How would you know whether 19 or not it's an inferior product without 20 the testing prior to marketing? 21 A. Studies on ULTRAPRO versus 22 Gynemesh did not show that ULTRAPRO was 23 an inferior product and had less mesh 24 load totally.</p> | <p>1 difference in the inflammatory processes 2 associated with the +M mesh as compared 3 to the Prolift mesh? 4 A. Again, in women's vaginas, 5 there's no study that has looked at the 6 evolution of the inflammatory process in 7 healthy women who have had this mesh 8 implanted by performing biopsy, serial 9 biopsies and analyzing them under the 10 microscope. 11 Q. So the answer is, no, you 12 don't know if there's any difference? 13 A. There is not anything 14 published out there about those 15 differences in specifically Prolift and 16 Prolift+M which are used in the pelvis. 17 Q. Have you ever seen any of 18 the microscopic examinations of the mesh 19 used in Prolift or the +M? 20 A. I have. 21 Q. Do you know if there's any 22 difference in degradation of the mesh 23 between the Prolift+M and Prolift? 24 A. Well, that would depend on</p> |
| <p>1 Q. Are you talking about in the 2 hernia application? 3 A. In the hernia applications, 4 yes. And we had safety and efficacy data 5 and study data on the Prolift, so now 6 we're improving on the actual mesh or 7 we're changing the mesh incorporating an 8 absorbable component. 9 Q. And do you know if there are 10 any differences in the scarring 11 associated with the use of +M versus 12 Prolift? 13 A. I don't think the studies 14 have specifically reported on scarring. 15 Q. How about the same question 16 with regard to foreign body reaction, 17 whether or not it's more or less with the 18 +M versus the Prolift? 19 A. I don't think there's any 20 study out there that have biopsied 21 women's vagina and mesh postoperatively 22 and make a comparative comparison. 23 Q. Do you have any 24 understanding whether or not there's a</p> | <p>1 your definition of degradation. 2 Q. And how do you define that? 3 A. It depends. 4 Q. On what? 5 A. You have to give me the 6 definition of what you think is a 7 degradation. Does a product disintegrate 8 to form dust and become totally 9 insufficient? Does it completely 10 disappear? We know the absorbable 11 portion of the Prolift+M will degrade, it 12 will be reabsorbed and it will disappear, 13 so that's a normal function of the 14 Monocryl. 15 Q. Okay. Have you ever read 16 any of the depositions of Ethicon 17 employees? 18 A. No, I have not. 19 Q. So since your deposition in 20 Hammons for example you haven't read the 21 deposition of Axel Arnaud? 22 A. I have not. 23 Q. You haven't seen any emails 24 from Axel Arnaud saying that he thinks</p> |

| | |
|--|--|
| <p style="text-align: right;">Page 94</p> <p>1 the company should not do a clinical 2 trial of the Prolift+M because it might 3 be risky?</p> <p>4 MS. GRAFF: Objection.</p> <p>5 THE WITNESS: None of that 6 if it exists was ever provided to 7 me, so I have not read it.</p> <p>8 BY MR. ZONIES:</p> <p>9 Q. Ethicon never provided 10 documents like that to you; correct?</p> <p>11 MS. GRAFF: Object to form.</p> <p>12 THE WITNESS: Not to my 13 recollection.</p> <p>14 BY MR. ZONIES:</p> <p>15 Q. Did you ask for any 16 documents like that?</p> <p>17 A. Not in the preparation of 18 this report.</p> <p>19 Q. How about after the Hammons 20 deposition? Did you ask for any 21 documents as a result of the deposition 22 in Hammons? Did you say, hey, we 23 discussed such and so, I'd like to see 24 that document or that study?</p> | <p style="text-align: right;">Page 96</p> <p>1 Q. And I'm still a little 2 unclear. In your reliance materials you 3 have an expert report listed there from 4 Doctor Garely related to the Prolift+M 5 and I believe you said that you don't 6 know or you don't think you've reviewed 7 that expert report?</p> <p>8 A. As I sit here today, I don't 9 have a specific recollection if I have or 10 have not read it.</p> <p>11 Q. Assuming that Doctor Garely 12 had issued and Plaintiff's other experts 13 had issued expert reports on Prolift+M in 14 discussing their concerns with Prolift+M, 15 do you think having those reports and 16 reviewing those would have been helpful 17 in formulating your opinions in this 18 case?</p> <p>19 MS. GRAFF: Object to form.</p> <p>20 THE WITNESS: I've based my 21 opinions on medical literature, my 22 experience, what I've reviewed, so 23 I don't know if a work product or 24 a report for the opposite point of</p> |
| <p style="text-align: right;">Page 95</p> <p>1 A. No.</p> <p>2 Q. Would it have been something 3 that would have informed your opinion in 4 this case if you had known that Axel 5 Arnaud, one of the medical directors at 6 Ethicon, was of the opinion that doing a 7 study of the Prolift+M mesh as compared 8 to the Prolift mesh prior to the sale of 9 Prolift+M may have been risky?</p> <p>10 MS. GRAFF: Object to form.</p> <p>11 THE WITNESS: Would I have 12 wanted to know?</p> <p>13 BY MR. ZONIES:</p> <p>14 Q. Yeah.</p> <p>15 A. Retrospectively here? No.</p> <p>16 Q. That's not something you'd 17 want to have looked at?</p> <p>18 A. I've used the Prolift+M and 19 it would have to depend on the context of 20 that email.</p> <p>21 Q. But you've never seen it, so 22 you don't know what that context is; 23 correct?</p> <p>24 A. That would be correct.</p> | <p style="text-align: right;">Page 97</p> <p>1 view expert report provided by 2 Plaintiffs would have had a 3 significant impact on my report.</p> <p>4 BY MR. ZONIES:</p> <p>5 Q. If Doctor Garely had for 6 example literature in his report that he 7 discussed that was literature about the 8 Prolift+M that isn't listed in your 9 reliance materials, do you think it would 10 have been helpful for you to review the 11 literature he reviewed and opined on?</p> <p>12 MS. GRAFF: Object to form.</p> <p>13 THE WITNESS: It depends.</p> <p>14 BY MR. ZONIES:</p> <p>15 Q. And did you review Doctor 16 Garely's reliance materials?</p> <p>17 A. I don't think that was -- 18 I'm not sure if that was provided to me 19 or not.</p> <p>20 Q. If Doctor Garely had in his 21 reliance materials other internal Ethicon 22 documents discussing the testing or lack 23 of testing of the Prolift+M prior to its 24 marketing, is that something you would</p> |

| Page 98 | Page 100 |
|---|--|
| <p>1 have liked to have at least known about 2 in the preparation of your report? 3 MS. GRAFF: Object to form. 4 THE WITNESS: Would I have 5 wanted to know or needed to know? 6 It depends on what those articles 7 contained. They may have no 8 bearing on my opinion, so it 9 depends.</p> <p>10 BY MR. ZONIES:</p> <p>11 Q. But they may have a bearing, 12 you just don't know because you haven't 13 seen those materials, Ethicon hasn't 14 given them to you; correct?</p> <p>15 MS. GRAFF: Objection.</p> <p>16 THE WITNESS: I have not 17 seen the entire list of what 18 Doctor Garely relied on. Some of 19 his articles might be the same as 20 mine.</p> <p>21 BY MR. ZONIES:</p> <p>22 Q. But you don't know?</p> <p>23 A. As I sit here today, I don't 24 have his list, and since I only have</p> | <p>1 orders I'm not permitted to do so, 2 so thank you for your time on the 3 Prolift+M.</p> <p>4 THE WITNESS: You're 5 welcome.</p> <p>6 (Whereupon, the deposition 7 was concluded at approximately 8 1:27 p.m.)</p> |
| | Page 99 |
| <p>1 received this yesterday afternoon, I 2 haven't made a comparative or been able 3 to make a comparative note of what he 4 relied on.</p> <p>5 MR. ZONIES: Go off the 6 record for a second.</p> <p>7 (Whereupon, a brief recess 8 was held from 12:20 p.m. 12:26 9 p.m.)</p> <p>10 MR. ZONIES: Doctor Drolet, 11 we've reached our two-hour time 12 for the Prosima+M deposition so --</p> <p>13 THE WITNESS: No.</p> <p>14 MS. GRAFF: Prolift+M.</p> <p>15 THE WITNESS: Prolift+M.</p> <p>16 MR. ZONIES: What did I say?</p> <p>17 THE WITNESS: Prosima.</p> <p>18 MR. ZONIES: Doctor Drolet, 19 we've reached our two-hour time 20 limit for the Prolift+M 21 deposition, so I'm going to go and 22 stop now. I would like the 23 opportunity to discuss it further 24 with you, but under our current</p> | <p>1</p> <p>2</p> <p>3</p> <p>4 I, EILEEN P. BARTH, hereby certify 5 that the testimony and proceedings in the 6 foregoing matter are contained fully and 7 accurately in the stenographic notes 8 taken by me and are a true and correct 9 transcript of the same.</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> |
| | Page 101 |
| | <p style="text-align: center;">CERTIFICATION</p> <hr/> <p style="text-align: center;">EILEEN P. BARTH Certified Shorthand Reporter</p> <p style="text-align: center;">The foregoing certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or direction of the certifying shorthand reporter.</p> |

Page 102